IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TERRY PAULSEN, an individual, **Plaintiff,** **v.** **ABBOTT LABORATORIES, ABBVIE INC., TAKEDA PHARMACEUTICALS U.S.A., INC., and TAP PHARMACEUTICAL PRODUCTS, INC.,** **Defendants.**	**Case No. 1:15-cv-04144** **Judge Robert M. Dow, Jr.**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS ABBOTT LABORATORIES, ABBVIE INC., AND TAKEDA PHARMACEUTICALS U.S.A., INC.'S RULE 11 MOTION FOR SANCTIONS

Plaintiff's Second Amended Complaint, filed on July 6, 2018, purports to assert product liability and other claims against Abbott Laboratories ("Abbott"), AbbVie Inc. ("AbbVie"), and Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA"), as well as TAP Pharmaceutical Products, Inc. ("TAP"), arising out of injuries that Plaintiff allegedly sustained after her physician administered a prescription drug, Lupron Depot ("Lupron"), to Plaintiff nearly fifteen (15) years ago. That complaint—Plaintiff's sixth attempt—alleges that all of the named Defendants manufactured or participated in the manufacture of Lupron at the time she took the drug. In point of fact, however, discovery in this case has already demonstrated conclusively, and Plaintiff herself has previously acknowledged, that Takeda Chemical Industries, Ltd. ("Takeda Ltd."), an entity that this Court has dismissed from this case with prejudice—*and not any other entity*—manufactured the product at issue at the time of Plaintiff's alleged injury, making any allegations that *any* of the named Defendants manufactured or participated in the manufacture of the product at issue impossible, obviously false, and a clear violation of Rule 11's proscriptions.

These false allegations are neither innocent nor harmless. They permitted Plaintiff to survive a previous Rule 12 motion as to Abbott, and if allowed to proceed, will force Abbott, TPUSA, and newly-named defendant AbbVie to incur significant costs in defending against these allegations only to confirm (once again) that they are entirely made up. That is precisely the type of harm Rule 11 was enacted to prevent. For these reasons, and as explained in more detail below, the Court should strike these baseless allegations, award Abbott, AbbVie, and TPUSA their costs and attorneys' fees incurred in addressing this issue since the filing of the First Amended Complaint, and impose all other sanctions that the Court deems appropriate and just under the circumstances.

BACKGROUND

A. Procedural History

Plaintiff filed her initial complaint (substantially similar to the complaints in this action) in the Eastern District of New York on April 20, 2010. (*Cardenas & Paulsen v. Abbott Labs. et al.*, No. 10-CV-1745-RRM-VVP (E.D.N.Y.), Dkt. 1.) Over the course of several years while the original action was pending, Plaintiff had ample opportunity to litigate her claims, lodging multiple amended complaints (one of which was dismissed for failure to state a claim), filing a motion to dismiss defendants' statute of limitations defense (which was denied), and engaging in the exchange of substantial written discovery and discovery motion practice.

In October 2013, this Court dismissed the case for want of prosecution and entered judgment. (*Cardenas & Paulsen v. Abbott Labs. et al.*, No. 1:11-CV-04860 (N.D. Ill.), Dkt. 115-16.) The dismissal was subsequently vacated, and then shortly thereafter, on May 30, 2014, the case was voluntarily dismissed. (*Id.*, Dkt. 143-44.) Just short of a year later, on April 24, 2015, Plaintiff filed a Motion to Reopen her action, which the Court denied *sua sponte*. (*Id.*, Dkt. 146-47.)

Plaintiff filed her first complaint in this action on May 11, 2015. (Dkt. 1.) Defendants moved to dismiss on a number of grounds on July 6, 2015. (Dkt. 25-26, 28-29.) On November 20, 2015, the Court allowed Plaintiff additional briefing to address which state's law governed the refiling of her complaint (Dkt. 49), and on January 6, 2016, allowed her to conduct discovery regarding Abbott's contention that it is not a real party in interest as to Plaintiff's claims in this case, such that the Illinois Borrowing Statute categorically time-bars Plaintiff's claims (Dkt. 52). The scope of that discovery is discussed further below. Abbott moved for summary judgment on the issue of real party in interest on August 24, 2016. (Dkt. 70-71.) That motion was denied March 15, 2017. (Dkt. 94-95.)

On April 7, 2017, Abbott, TPUSA, Takeda Ltd., and TAP filed renewed motions to dismiss pursuant to Rules 12(b)(5), 12(b)(6), and 9(b). (Dkt. 96-97, 99-100.) On March 27, 2018, Defendants' motions to dismiss were granted in part and denied in part. (Dkt. 110-111.) Plaintiff's claims against Abbott for strict liability and strict products liability—failure to warn were allowed to proceed because Plaintiff had alleged "some participation on Abbott's part in Lupron manufacturing beyond its ownership of TAP[.]" (Dkt. 111, Mem. Op. and Order, at 28.)

The Court dismissed all claims as to TPUSA (formerly known as TPNA), ruling that Plaintiff had failed to allege any fact that "connects TPNA to TAP and its alleged responsibility for Lupron-related activities, beyond their shared parent company [Takeda Ltd.]." (*Id*. at 21 (concluding that "Plaintiff simply has not alleged that TPNA was at all involved in TAP's activities relating to Lupron, and without such allegations her claims against TPNA are not plausible.").) The dismissal, however, was without prejudice. (*Id.* at 22.)

All claims against TAP were dismissed, but Plaintiff was given until May 22, 2018 to serve an amended complaint upon a proper defendant. (*Id.* at 17-18.) All claims against Takeda

Ltd. and Takeda Chemical Industries, Inc. ("Takeda Inc.") were dismissed with prejudice.[1] (*Id.* at 19.)

B. Plaintiff's Latest Complaint

On April 24, 2018, Plaintiff filed her First Amended Complaint, which attempted to resuscitate previously-dismissed claims against Abbott, TPUSA, and TAP, and purported to assert new claims against AbbVie. (Dkt. 117.) In response and in accord with the procedure required by Federal Rule of Civil Procedure 11, Abbott, AbbVie, and TPUSA served Plaintiff's counsel with a draft Rule 11 motion and asked her to withdraw certain allegations, including, among others, allegations that any of the named Defendants manufactured or participated in the manufacture of the product at issue at the time Plaintiff took it. Thereafter, Defendants' and Plaintiff's counsel participated in a number of meet and confers regarding the allegations that were the subject of the draft Rule 11 motion, and Plaintiff agreed to amend her complaint. (Dkt. 140, 142 (Plaintiff seeking and order allowing leave to amend).)

Plaintiff filed her Second Amended Complaint on July 6, 2018. (Dkt. 143.) The Second Amended Complaint, however, still includes allegations that Plaintiff knows to be false and unsupported. Specifically, in Paragraphs 25, 34, 35, 39, and 42 of her Second Amended Complaint, Plaintiff has at least attempted to allege as fact that Abbott and TAP manufactured Lupron, the drug she alleges she took in February and March 2004, and from which she alleges her injuries arose. Similarly, in Paragraphs 26, 27, and 45, Plaintiff has alleged that the drug at issue was "manufactured" by all of the currently-named Defendants (Abbott, AbbVie, TPUSA, and TAP). (*See* Dkt. 143, Second Am. Compl. ("SAC") at ¶ 26 ("Lupron was expected to and did, in fact, reach consumers without substantial change in the condition in which Lupron was

[1] Throughout briefing in this case, Plaintiff has repeatedly confused or conflated Takeda Ltd. with "Takeda Chemical Industries, Inc.," which does not exist. Regardless, "any claims against either entity are indisputably time-barred," and have been dismissed with prejudice. (Dkt. 111, Mem. Op. and Order, at 18-19.)

produced, formulated, *manufactured*, sold, distributed, labeled and packaged and marketed by the Defendants.") (emphasis added); *id*. ¶ 27 ("At all times herein described, Lupron was in an unsafe, defective, and inherently dangerous [sic] and was hazardous to users, and specifically to the Plaintiff in the condition in which the Lupron was produced, *manufactured*, sold, distributed, labeled and packaged, and marketed by the Defendants.") (emphasis added); *id*. ¶ 45 ("Based on what they knew or reasonably should have known as described above, each of the Defendants deviated from the standard of care and breached their duty and were otherwise negligent in one or more of the following particulars: a. in formulating, analyzing, designing, fabricating, *manufacturing*, supplying, distributing, advertising, promoting, packaging, marketing, selling and recommending Lupron in its defective condition, Defendant Abbott and TAP knew or should have known….") (emphasis added).)

Discovery in this case, however, has already demonstrated conclusively, and Plaintiff herself has previously acknowledged, that Takeda Ltd., an entity that this Court has dismissed from this case with prejudice—and *not* Abbott, AbbVie, TPUSA, or TAP, or any other entity—manufactured the product at issue at the time Plaintiff allegedly took it. On January 6, 2016, in its order on the parties' supplemental briefing regarding the statute of limitations, the Court allowed Plaintiff to take discovery regarding "Abbott's contention that it is not a real party in interest because it neither manufactured, distributed, or sold the Lupron at issue nor is a successor in liability to a company that did so." (Dkt. 52 at 6.) In response to that order, Plaintiff, represented by current counsel, served Abbott with 37 requests for production, 28 requests for admission, and 7 interrogatories, each containing multiple subparts, many going to the heart of this very question—what entity manufactured Lupron during the relevant timeframe. (Dkt. 65 at 2.)

For example, in Plaintiff's Requests for Admission, she asked Abbott to "Admit that Abbott would be regarded as the manufacturer of Lupron because of the Joint Venture Agreement with Takeda"; "Admit that Lupron was one of the pharmaceutical products that was manufactured by Takeda[2] because of the Joint Venture Agreement"; and "Admit that the Joint Venture Agreement allowed Takeda to manufacture of [sic] Lupron." (*See* Abbott's Responses to Plaintiff's Second Set of Requests for Admission, attached as Ex. A,[3] at ¶¶ 8, 16, 18.) Abbott consistently responded that Takeda Ltd.—and not any of the currently-named Defendants—was the manufacturer of the product during the relevant timeframe. (*Id.*)

Similarly, in Plaintiff's Requests for Production, she asked for "Any and all documents that relate to or show that Abbott participated in the manufacture of Lupron pursuant to the Joint Venture Agreement with Takeda"; "Any and all documents that refer to or show that Lupron was one of the pharmaceutical products that was manufactured by Takeda because of the Joint Venture Agreement"; "Any and all documents that relate or show that the Joint Venture Agreement allowed Takeda to manufacture of Lupron"; and "Any and all documents that relate to or show that Lupron was manufactured by Takeda as part of the Joint Venture Agreement." (*See* Abbott's Responses to Plaintiff's Second Set of Requests for Production, attached as Ex. B, at ¶¶ 8, 16, 18, 28.) In response, Abbott produced nearly 1,000 pages of documents (Dkt. 65 at 2), including, among other documents, the Lupron 2004 label, revised March 2003 (attached as Ex. C) and the Lupron 2005 label, revised February 2004 (attached as Ex. D), both of which confirmed that Takeda Ltd. alone—and not any of the currently-named Defendants—

[2] Plaintiff defined "Takeda" as "defendants Takeda Chemical Industries, Ltd. (also known as Takeda Pharmaceutical Company Limited) and Takeda America Holdings, Inc."—none of the current Defendants.

[3] The Exhibits referenced in this Memorandum of Law are the same Exhibits referenced in and filed as exhibits to the Rule 11 Motion for Sanctions.

manufactured Lupron during the relevant timeframe. At no time during the course of discovery or subsequent briefing on this issue did Plaintiff offer any evidence to the contrary.

In fact, Plaintiff conceded as much in response to Abbott's previous motion for summary judgment. In Abbott's Local Rule 56.1 Statement of Material Facts, filed along with its Motion for Summary Judgment, Abbott provided evidence showing that "Abbott did not manufacture, sell, or distribute the Lupron plaintiff alleges she was administered in February and March 2004. In 2004, Lupron was manufactured by [Takeda Ltd.] in Osaka, Japan[.]" (Dkt. 72 at ¶ 7.) As support Abbott cited the two Lupron labels discussed above. (Exs. C-D.) In her response to Abbott's Statement of Material Facts, Plaintiff did not dispute who *manufactured* Lupron, only whether Abbott *distributed* that product for use in the United States. (Dkt. 81 at ¶ 7.) Plaintiff cited no evidence contrary to Abbott's statement that Takeda Ltd. manufactured the Lupron at issue (nor could she). (*Id.*) Further, in Plaintiff's Opposition to Defendant Abbott Laboratories' Motion for Summary Judgment on the Threshold Issue of Real Party in Interest *she herself asserted* that Takeda Inc. manufactured the Lupron product at issue in this case during the relevant timeframe. (Dkt. 80 at 2 (Plaintiff asserting that "Lupron was manufactured by Defendant Takeda Chemical Industries, Inc.").) Plaintiff also included this statement in her own Rule 56.1 Statement of Material Facts. (Dkt. 81 at Section II, ¶ 2.e. ("Lupron was manufactured by Takeda[.]").)

Thus, despite having ample time for discovery into the question of what entity manufactured the product at issue, Plaintiff has failed to locate or produce any evidence to support her allegation that any (much less all) of the currently-named Defendants manufactured or participated in the manufacture of that product, and, to the contrary, Plaintiff herself has previously asserted that the manufacturer was Takeda Inc.

Pursuant to Rule 11(c)(2), counsel for Abbott, TPUSA, and AbbVie served the accompanying Motion on Plaintiff on July 13, 2018. (Ex. E (service email and copy).)[4] As of the date of this filing, however, Plaintiff has not withdrawn the allegations at issue.

ARGUMENT

Rule 11 provides, among other things, that "[b]y presenting to the court a pleading . . . an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: . . . the factual contentions have evidentiary support[.]" Fed. R. Civ. P 11(b)(3). In other words, Rule 11 requires "adequate investigation before filing a complaint. It is not permissible to file suit and use discovery as the sole means of finding out whether you have a case." *Szabo Food Serv., Inc. v. Canteen Corp*., 823 F.2d 1073, 1083 (7th Cir. 1987). In clarifying the standard for adequate investigation, the Seventh Circuit has held that "[t]he amount of investigation required by Rule 11 depends on both the time available to investigate and on the probability that more investigation will turn up important evidence[.]" *Id*.

Courts have held that this duty to investigate requires "that counsel not rely solely upon the allegations made by the client, but that they also conduct an independent inquiry into the facts. An attorney must investigate the relevant facts . . . to determine whether the facts support a recognized entitlement to relief." *Muraoka v. Am. Osteopathic Ass'n*, 117 F.R.D. 616, 618 (N.D. Ill. 1987) (citations omitted); *see also Szabo*, 823 F.2d. at 1083 ("Rule 11 requires independent inquiry."); *Jordan v. Brady*, No. 92 C 2229, 1993 WL 96127, at *2 (N.D. Ill. Apr. 1, 1993) ("Rule 11 requires . . . that an attorney conduct a reasonable, independent investigation into the facts of a case before filing a complaint."). Moreover, whether an attorney's pre-filing

[4] The Rule 11 Motion served on Plaintiff pursuant to Rule 11(c)(2) and the Motion filed contemporaneously herewith are identical, except that a parenthetical identifying the "service email and copy" as Ex. E was added to the filed version. (*Compare* filed Motion *with* Ex. E.)

investigation was reasonable under the circumstances is an "objective determination." *D'Aquino v. Citicorp/Diner's Club, Inc*., 139 F.R.D. 357, 360 (N.D. Ill. 1991). "A sanctioned attorney's good faith is immaterial if his conduct was objectively unreasonable." *Id*.; *see also Noga v. Kimco Corp*., No. 96 C 6108, 1997 WL 639233, at *3 (N.D. Ill. Oct. 7, 1997).

Here, there can be no reasonable dispute that Plaintiff's factual allegations that the named Defendants manufactured or participated in the manufacture of Lupron at the time that Plaintiff allegedly took it are false and without any evidentiary support whatsoever. Moreover, Plaintiff's refusal to withdraw these allegations cannot be chalked up to a simple misunderstanding. As noted above, Plaintiff had ample opportunity to—and did—take discovery on this very issue. That discovery confirmed (and Plaintiff has previously conceded) that Takeda Ltd.—and not any of the currently named Defendants—manufactured the product at issue at the time of Plaintiff's alleged injuries. Thus, it is facially implausible that Plaintiff did not know who manufactured the product at issue at the time she filed her latest complaint. This conduct is not only objectively unreasonable—meeting the requirements for a Rule 11 violation—but also plainly crosses the line into bad faith. *See N. Trust Co. v. Muller*, 616 F. Supp. 788, 790 (N.D. Ill. 1985) ("[A] lawyer engages in bad faith by acting recklessly or with indifference[.]").

These baseless allegations are far from being harmless. As this Court previously explained, to state a valid claim for strict liability under Georgia law, a plaintiff must establish "that the product or products that allegedly caused [the injury] were, in fact, manufactured or supplied by the defendants in th[e] case." (Dkt. 111, Mem. Op. and Order, at 27 (quoting *Swicegood v. Pliva,, Inc.*, 543 F. Supp. 2d 1351, 1355 (N.D. Ga. 2008)).) "A defendant that is not the manufacturer of an allegedly defective product cannot be held strictly liable under a theory of strict liability." (*Id*. (citing *Vax v. Albany Lawn & Garden Ctr.*, 433 S.E.2d 364, 366

(Ga. Ct. App. 1993)).) Thus, the previous complaint's false allegations as to the entity that manufactured the product at issue, repeated in Plaintiff's Second Amended Complaint, are critical to the survival of her strict liability claims. In fact, the Court relied on similar allegations in denying Abbott's previous Rule 12 motion on Plaintiff's strict liability claims. (*Id.* at 28 (allowing Plaintiff's claims against Abbott for strict liability and strict products liability—failure to warn to proceed because Plaintiff had alleged "some participation on Abbott's part in Lupron manufacturing beyond its ownership of TAP").) Thus, as a direct consequence of Plaintiff's false allegations, this Court needlessly expended considerable resources on, amongst other things, deciding Abbott's previous motion to dismiss. And, if the allegations are allowed to stand, the named Defendants will be forced to incur significant costs of defending against these baseless allegations only to confirm (once again) that they are completely false. While sanctions are appropriate even absent a finding of harm, the costs to the Court and the parties in this case provides additional justification for imposing sanctions.

Given "the essential purpose of Rule 11 [] to force attorneys to make inquiries before they file a paper in court[,]" significant sanctions are warranted to deter Plaintiff's counsel from their pattern of reckless conduct. *Williams v. Balcor Pension Inv'rs*, No. 90 C 0726, 1995 WL 23061, at *1 (N.D. Ill. Jan. 17, 1995); *see also Brandt v. Schal Assocs., Inc*., 960 F.2d 640, 646 (7th Cir. 1992) ("[O]ne of the goals of Rule 11 is to impose costs on the careless or reckless lawyers.") (citation omitted) (alteration in original). The manufacturing allegations in the Second Amended Complaint are concededly and materially false. Counsel was provided the required time to correct the falsity, but no correction was made. Under Rule 11(c), then, this Court can and should strike the allegations referenced above for which Plaintiff has no good-faith basis for asserting in her Second Amended Complaint, dismiss all claims based on such

allegations, and award the named Defendants the attorneys' fees and costs they have expended since receipt of the First Amended Complaint.

CONCLUSION

For all of these reasons, Abbott, AbbVie, and TPUSA respectfully request that this Court impose Rule 11 sanctions on Plaintiff Terry Paulsen and/or her attorneys, Alan S. Levin and Tesfaye W. Tsadik, and their respective law firms, Alan S. Levin, P.C. and Law Office of Tesfaye W. Tsadik, including, among other potential sanctions, striking the allegations referenced above for which Plaintiff has no good-faith basis for asserting in her Second Amended Complaint, dismissing all claims based on such allegations, and awarding the named Defendants the attorneys' fees and costs associated with filing this Motion, and all other appropriate sanctions against Plaintiff and/or her attorneys that the Court deems just and appropriate.

Dated: August 6, 2018

Respectfully submitted,

/s/ *Kathryn L. Dore*

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CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2018, I electronically filed the foregoing **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS ABBOTT LABORATORIES, ABBVIE INC., AND TAKEDA PHARMACEUTICALS U.S.A., INC.'S RULE 11 MOTION FOR SANCTIONS** with the Clerk of the Court using the CM/ECF system, which will send notification to all counsel of record.

/s/ Kathryn L. Dore
Attorney for Defendants Abbott Laboratories, AbbVie Inc., and Takeda Pharmaceuticals U.S.A., Inc.